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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO CONFIRMATION NO. Ivars V. Ivansons DENCO-53 1954 10-077,03× 02:15-2002 07.30/2003 7590 Connolly Bove Lodge & Hutz LLP EXAMINER P.O. Box 2207 DRODGE, JOSEPH W Wilmington, DE 19899-2207 ART UNIT PAPER NUMBER

> 1723 DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/077,038	IVANSONS ET AL				
Office Action Summary	Examiner	Art Unit				
	Joseph W. Drodge	1723				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1) Responsive to communication(s) filed on 15 F	ebruary 2002					
	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
4) Claim(s) 1-30 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) 1,2,18,19,22-26 and 30 is/are rejected.						
7)☑ Claim(s) <u>3-17,20,21 and 27-29</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3	5) Notice of Informal F	(PTO-413) Paper No(s)				
S Patent and Trademark Office PTO-326 (Rev. 04-01) Office Act	ion Summary	Part of Paper No. 5				



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Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23, a "," is needed after "membrane" in line 2 for clarity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ameer et al patent 6,099,730.

Ameer et al disclose method and apparatus for purifying blood using a centrifuge (column 8, lines 22-35, figures 3 and 4) having filters 58 and 60 within, and having "fluid" and "purifying fluid" supply lines [as in claim 2] and "purified fluid" (heavier phase) and relatively contaminated fluid (lighter phase) discharge lines (column 8, lines 13-21).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.



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2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 19, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ameer et al in view of laconelli patent 3,520,803.

The claims differ in requiring the purifying chamber to comprise a filter in the form of a stack of parallel membranes. Such membrane filter stack is taught by laconelli in membranes 18 and 19 as useful for membrane filtrations including dialysis (see column 1, lines 45-66, column 3, lines 44-75 and column 11, lines 60-63). It would have been obvious to one of ordinary skill in the art to have substituted a membrane filter stack for the planar membranes disclosed by Ameer et al, as taught by laconelli, to achieve higher degrees of separation and concentration of fluid (blood) components and to be able to process higher volumes of fluid.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ameer et al in view of Shaposka et al patent 5,141,592.



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Claim 30 differs in requiring removal of blood from the patient and return of blood thereto through supply and discharge lines to include cutting through and sealing of the tubes and reconnecting and opening of the lines through use of a sterile connection device in each line. Such procedure is taught by Shaposka et al in column 2, lines 7-45 and column 10, lines 10-25. It would have been obvious to one of ordinary skill in the art to have utilized such cutting, sealing and reconnection with sterile connection devices as taught by Shaposka et al in the method of Ameer et al, in order to minimize the need for syringe needles and hence enhance safety by doing away with the need for disposal of biological hazardous waste.

Claims 3-17, 20, 21 and 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

These claims are all distinguished in view of respective recitations of the purifying chamber comprising a plurality of co-arcuately aligned modules. Ameer et al only teach individual filters and laconelli teach rigid, rectangular plate and frame type stacks of membranes filter modules. Such limitation non-obviously achieves improved combined centrifugal and filtering separation of fluid components.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by laconelli patent 3,520,803.

laconelli discloses a membrane dialyzer (column 5, line 41 and column 11, lines 56-63) that comprises a stack of alternately arranged plates 12,14,C-13 and B-13, membranes 10, the plates having longitudinal centrally located channels E8, D8, C8 AND B8, covers

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11, means to supply and discharge fluids (column 5, lines 14-30) and means to seal (see the gaskets described in column 4, lines 34-38).

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 24 distinguishes over the closest prior art deemed to constitute laconelli in the recitation of longitudinal flow channels forming a sawtooth flow pattern with each plate having flow channels at one end in a centrally located set and flow channels at the other end in two spaced sets.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fishel patent 5,464,534 and Shmidt et al patent 4,790,942 are of interest in recitation of blood dialysis or fractionation occurring in centrifuges having filters along the outside of the outer surfaces of rotating members. Raj patent 4,229,920 is of interest with respect to a blood dialyzer comprising membranes inserted between 3 stacked plates that each have flow channels.

JWD

5-24-2003

JOSEP DRODGE PRIMARY EXAMINER